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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
08/846,658	05/01/1997	JOHN ROBERT ADAIR	CARP-0057	9631

7590 12/18/2001

FRANCIS A PAINTIN
WOODCOCK WASHBURN KURTZ
MACKIEWICZ AND NORRIS
ONE LIBERTY PLACE 46TH FLOOR
PHILADELPHIA, PA 19103

EXAMINER

DAVIS, MINH TAM B

ART UNIT PAPER NUMBER

1642

DATE MAILED: 12/18/2001

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

08/846,658

Applicant(s)

ADAIR et al

Examiner

MINH TAM DAVIS

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on Sep 13, 2001.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 24-31 is/are pending in the application.
- 4a) Of the above, claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 24-31 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

*See the attached detailed Office action for a list of the certified copies not received.

- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☐ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☐ Other:

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Effective February 7, 1998, the Group Art Unit location has been changed, and the examiner of the application has been changed. To aid in correlating any papers for this application, all further correspondence regarding this application should be directed to Minh-Tam Davis, Group Art Unit 1642.

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 09/13/01 has been entered.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Accordingly, claims 24-31 are being examined.

The following are the remaining rejections.

REJECTION UNDER 35 USC 102 (e)

Rejection under 35 USC 102(e) of claims 24-31 pertaining to anticipation by Queen et al remains for reasons already of record in paper No.35.

Applicant argues that the limitation "outside the Kabat and Chothia CDRs" was not supported in the Queen '975 and '252. The passages on page 9, lines 1-5 of Queen '975 and page 13, lines 1-8 or Queen '252 do not even refer to CDRs. The sentence does not explicitly refer to

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Chothia CDRs. The sentence refers to hypervariable regions, which are also called CDRs, and cites two references Kabat et al and Chothia et al. This passage does not provide support for the claimed limitation. In addition, the statement by the Examiner that Chothia et al define CDRs is erroneous. Chothia et al do not define CDRs. Chothia et al describes six hypervariable loops, which it carefully distinguishes from the Kabat CDRs. When Chothia et al refers to CDRs, it is referring to the Kabat CDRs. One of skill in the art could not have recognized that the CDRs taught by Queen '975 include CDRs as defined by Chothia et al. Applicant encloses a copy of the "Interlocutory decision in Opposition proceedings" in which the Opposition Division concluded that there is no convincing evidence for an alternative or refined definition of Kabat et al's CDRs by Chothia et al. Chothia et al simply establish the concept of the hypervariable loop by determining the residues controlling the 3-dimensional conformation as opposed to Kabat's definition of a CDR strictly relying on residues determining the sequence variability. To this end, Chothia et al accepted the CDR definition of Kabat based on sequence hypervariability and merely compared his data to the Kabat CDR's, by using the Kabat numbering system.

Applicant's arguments set forth in paper No. have been considered but are not deemed to be persuasive for the following reasons:

Contrary to Applicant's assertion, the limitation "outside the Kabat and Chothia CDRs" was supported in the Queen '975 and '252, including in their parent case No: 07/290975 . Since Queen et al in the specification of the parent case No: 07/290975 incorporate by reference the definition of CDR's by Chothia et al, in addition to the CDR's as defined by Kabat, one of

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ordinary skill in the art would have recognized that CDR's as taught by Queen et al would include also CDR's as defined by Chothia et al, besides CDR's as defined Kabat et al, regardless of whether the rest of the specification discloses as examples Kabat's CDR's.

Queen et al (07/290975, p. 8 last paragraph, bridging p.9) teach that the variable regions form the antibody binding site, exhibiting conserved framework regions joined by hypervariable regions, which are also called CDR's. Chothia et al teach a precise structural distinction between the two parts of the variable domains: the conserved beta-sheet framework and the regions of variable main-chain conformation (page 904, first column). In other words, the regions of variable main-chain conformation are equivalent to the hypervariable regions. Chothia et al also teach identification of the residues that determine the conformations of the hypervariable region (p.915, second column), and that these residues are available for binding to antigens and are largely those in the structurally variable regions, defined as residues 26-32, 50 to 52, and 91-96 in VL domain, and 26 to 32, 53 to 55 and 96 to 101 in the VH domain (page 914). Chothia et al further teach that the limits of the main-chain conformation are somewhat different from those of the CDRs regions defined by Kabat et al, based on sequence variability (p. 904). Chothia et al further teach that if the identified residues are found in the sequences of other immunoglobulins, their hypervariable regions will have the same conformation (p.915, second column). Although Chothia et al do not specifically recite that CDRs are defined as residues 26-32, 50 to 52, and 91-96 in VL domain, and 26 to 32, 53 to 55 and 96 to 101 in the VH domain, however, these residues are available for binding to antigens, and form the second, variable part of the variable

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domain, which is the same as the hypervariable domain. Thus the defined residues taught by Chothia et al, which determine the conformation of the hypervariable regions, are not any different than the hypervariable domain, which is the second part of the variable domain in addition to the framework regions, and is also called CDRs, as taught by Queen et al. In other words, Chothia et al prefer to identify the hypervariable regions by their conformation rather than by based on sequence variability, as defined by Kabat et al, because Chothia et al teach that modeling based on the sets of residues identified as responsible for the conformations of hypervariable regions would be expected to give more accurate results (p.902, first column, paragraph before last). Thus contrary to Applicant's assertion, Chothia et al do not merely compare their data to the Kabat CDRs.

All claims are drawn to the same invention claimed in the application prior to the entry of the submission under 37 CFR 1.114 and could have been finally rejected on the grounds and art of record in the next Office action if they had been entered in the application prior to entry under 37 CFR 1.114. Accordingly, **THIS ACTION IS MADE FINAL** even though it is a first action after the filing of a request for continued examination and the submission under 37 CFR 1.114. See MPEP § 706.07(b). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after

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the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Minh-Tam B. Davis whose telephone number is (703) 305-2008. The examiner can normally be reached on Monday-Friday from 9:30am to 3:30pm, except on Wednesday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tony Caputa, can be reached on (703) 308-3995. The fax phone number for this Group is (703) 308-4227.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (703) 308-0916.

Minh-Tam B. Davis

December 3, 2001

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MINH-TAM B. DAVIS
GROUP 1, PATENT EXAMINER